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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,251	03/27/2001	Hisao Hiramatsu	Q63803	8044

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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, DC 20037

EXAMINER
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SOOHOO, TONY GLEN

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/817,251

Applicant(s)

HIRAMATSU ET AL.

Examiner

Tony G. Soohoo

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9-23-2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Claim interpretation**

1. Claims 19 and 21 point out the use of the method in an apparatus. it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 7, 11, 13-15, and 17-21 are rejected under 35 U.S.C. 103(a) as obvious over JP 62-184357 in view of Knobel 5482863 (both previously cited).

The JP 62-184357 (JP '357) reference discloses as seen in figures 1 (i) through IV), as described in the supplied translation an automatic controlled repeated sucking and discharge of fluid on to the surface of the remaining liquid in a container to provide stirring. The translation states:

First, the liquid A is preliminarily present on the bottom of the container (4) in Figure 1 (i). The pipet (1), which has already suctioned the liquid B, becomes inserted into the container (4) in this state, and the liquid B is then extruded. The liquid A and liquid B therefore become mutually mixed, although a sufficient agitation state has yet to arise.

In Figure 1 (ii), the distal end of the pipet becomes lowered and then immersed underneath the liquid surface of the liquid mixture A + B. A certain volume (e.g., a half of total volume) is then suctioned.

Next, in Figure 1 (iii), the distal end of the pipet becomes elevated in a state where the liquid mixture remains suctioned and then positioned above the liquid surface of the liquid mixture stocked within the container. The liquid within the pipet becomes extruded in this state.

In Figure 1 (iv), furthermore, the state of Figure 1 (ii) becomes restored at the distal end of the pipet. In other words, the pipet distal end is lowered underneath the liquid surface in preparation for suction.

The pipet descension & suction and pipet ascension & extrusion actions discussed above are repeated within a single container.

#### F. Functions

The liquid within the container becomes sufficiently agitated physically as a result of the repetitions, via an interface provided by the liquid surface of the liquid within said container, of pipet descension & suction and pipet ascension & extrusion actions. The agitation is predicated on liquid countercurrents arising as a result of suction and on the collision of the extruded liquid with the liquid plane, etc.

The JP '357 reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of the step of where the discharge position is positioned at a horizontally different position from the sucking position. It is noted that the nozzle initially is empty thereby having air in the nozzle before the sucking step.

The reference to Knobel 5482863 (Knobel '863) teaches that it is desirable to discharge a liquid into a container at two different horizontal points thereby creating two vortex flows, column 3, lines 47-64, to enabling the solid phase to be suspended exclusively by injection of reagent, thus avoiding the need for a subsequent shaking operation.

12) The inventive process is suitable for other applications in addition to suspending particles deposited at diametrically opposite regions on the wall, relative to the central longitudinal axis. After a portion of the predetermined volume of reagent liquid has been pipetted into the reaction

Art Unit: 1723

vessel in a first position, the pipetting needle can be rotated to any desired second position at a distance from the central longitudinal axis of the reaction vessel, where the deposited particles are suspended by adding the remaining part-volume of reagent liquid. In addition, a solution already in the reaction vessel can be efficiently mixed with other solutions.

(13) A main advantage of the present invention is that addition of reagent liquid at two different positions in a reaction vessel results in a flow therein, enabling the solid phase to be suspended exclusively by injection of reagent, thus avoiding the need for a subsequent shaking operation. In analytical equipment, the inventive device can produce an optimum suspension of particles during the addition of reagent, simply by choosing a suitable program for actuating the pipetting needle, so that a maximum number of samples can be processed per unit time.

And column 4 lines 32-40:

(20) FIG. 3 shows the pipetting needle 18 in a first position at a distance  $e$  from the central longitudinal axis 22, where a part of the predetermined volume of reagent liquid 21 is injected. The resulting vortex 24 is diagrammatically shown.

(21) FIG. 4 shows the pipetting needle 18 in the second position at a distance  $e$  from the central longitudinal axis 22, where the rest of the predetermined volume of reagent liquid 21 is injected. The resulting vortex 25 is diagrammatically indicated, showing the reverse direction of rotation.

Also, on column 4, lines 52-64, the reference teaches that the distance of the position whereby the pipet is moved for dispensing may be readily varied:

(25) The invention has been described in terms of its preferred embodiments. However, upon reading the present specification various alternative embodiments will become obvious to those skilled in the art. For example, travel distance ( $e$ ) can be readily varied, as can the type of pipetting device, type of reaction container, processing station, etc.

In view of the teaching of the Knobel '863 reference that it is desirable to inject the fluid from the pipette from two different horizontal points thereby creating any solid phase to be suspended exclusively by injection of reagent, thus avoiding the need for a subsequent shaking operation, it is deemed that it would have been obvious to one of

Art Unit: 1723

ordinary skill in the art to provide for the method taught by the JP '357 reference with an additional step of injection of the A+B material into the container with the additional step of injection of the material in to different longitudinal horizontal locations so that addition vortex flows are produced in the container in order to more effectively suspend any solid phase.

With regards to the material in which the method of stirring is worked upon, the claim is directed to a method for stirring a liquid. Object "for.. a liquid" deemed as an environment of the stirring method. Is It is noted that the manipulation of fluid as presented by the JP '357 in view of Knobel '863 is fully capable of acting upon any liquid including blood. Whereby the type of fluid used does not perfect or affect the stirring manipulation in a positive sense of fluid dynamics, little patentable distinction is afforded to the use of blood in perfection of the stirring. Nonetheless it is deemed that it would have been obvious to one of ordinary skill in the art to use the method of JP '357 as modified whereby the processing of blood by a pipette is old and well known.

With regards to differing positions of the sucking and dispensing positions whereby Knobel '863 reference discloses that the distances of the injection may be varied, it is deemed that it would have been obvious to one of ordinary skill in the art to modify the positions of suction and discharge positions so as to provide a more effective suction flow or vortex flow.

With regards to claims 19 and 21, the recitation of the use of the method in an inspection apparatus does not point out a positive manipulative step in the perfection of stirring a fluid thereby has been afforded little patentable distinction, the recited

Art Unit: 1723

structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

4. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62-184357 in view of Knobel 5482863 as applied to claims 1, 11 respectively above, and further in view of JP 64-27626 (all cited previously).

JP 62-184357 in view of Knobel 5482863 discloses all of the recited subject matter as defined within the scope of the claims with the exception of the step of discharging air. It is noted that the nozzle initially is empty thereby having air in the nozzle before the sucking step.

The JP 64-27626 (JP '626) reference teaches that air maybe sucked into a discharge nozzle and discharged with the sample into the container causing air bubbles to further mix the fluid component.

Accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to further provide the JP '357 as modified above, an additional step of sucking in air into the pipette so that air may also be discharged with the fluid components to provide bubbles to cause further mixing and stirring.

5. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62-184357 in view of Knobel 5482863 as applied to claims 1, 11 respectively above, and further in view of Makino et al 5555767 (all previously cited).

JP 62-184357 in view of Knobel 5482863 discloses all of the recited subject matter as defined within the scope of the claims with the exception of using a container with an inclined wall of the structural type recited in the claims.

The Makino et al reference shows examples which a pipette may be used to mix liquid in a container which may have vertical walls figure 2 or alternately with walls with an incline as see in figure 3 or 5, column 5, lines 26-32. Accordingly, absent any unexpected results, it is deemed that it would have been obvious to one of ordinary skill in the art to substitute for the type of container of the type used by JP '357 with a commonly known functional equivalent container which may hold materials for a pipette, such as the type of container having walls at an incline as shown by Makino et al so that liquid dispensed by the pipette may more easily flow down from the sidewalls for good stirring performance.

6. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62-184357 in view of Knobel 5482863 as applied to claims 1, 11 respectively above, and further in view of EP 0527059 (all previously cited).

JP 62-184357 in view of Knobel 5482863 discloses all of the recited subject matter as defined within the scope of the claims with the exception of discharging the liquid a position limited in a horizontally external position to the sucked position (claims 22-23) or sucked near the center of the container.

EP 0527059 on form PTO-1449 is especially noted as a further example of the state of the art whereby it is known and desirable to automatically move the position of



the suction and discharge to various positions during the operation of a pipette for mixing in a container.

In light of the EP 5027059 (EP '059) reference that one may move a nozzle to various positions for sucking or dispensing a pipette for mixing, without undue experimentation, it is deemed that it would have been obvious to one of ordinary skill in the art to modify or limit the positions of the sucking and discharge any appropriate position so that mixing is optimized.

### ***Response to Arguments***

7. Applicant's arguments filed 9-23-2005 have been fully considered but they are not persuasive.

8. Applicant argues on page 9 in the remarks of the response filed 9-23-2005 that there is no reason to combine the teachings of JP '357 with Knobel. Applicant argues that J: 357 is directed to agitating liquid using a pipette and automatic control while Knobel is directed to an analytical device thereby has different purpose and different means. In response, the application of Knobel is directed to the art of laboratory equipment control of fluid processing utilizing fluid dispensing and filling and in particular fluid mixing, thus it is deemed that a person having ordinary skill in the art would look to such art in optimizing the fluid processing and would find it analogous art and have motivation to combined the JP '357 reference with the teachings of the Knobel reference, as discussed in detail in the rejection made above.

9. In response that the Rule 132 Declaration filed Dc 24, 2003 that the JP '357 would be difficult to agitate whole blood, the declaration does not provide sufficient evidence that the a mere difficulty in processing a more viscous fluid such as blood would render the combination unobvious in processing a thicker fluid such as blood.

10. Applicant also argues that the JP '357 teaches away from discharging the liquid directly into the liquid remaining in the container. This is unpersuasive applicant is referred to the translation of JP '357 which teaches

In Figure 1 (ii), the distal end of the pipet becomes lowered and then immersed underneath the liquid surface of the liquid mixture A + B. A certain volume (e.g., a half of total volume) is then suctioned.

Next, in Figure 1 (iii), the distal end of the pipet becomes elevated in a state where the liquid mixture remains suctioned and then positioned above the liquid surface of the liquid mixture stocked within the container. The liquid within the pipet becomes extruded in this state.

The reference to Knobel is cited to teach the differences of where the discharge position is positioned at a horizontally different position from the sucking position.

11. Applicant's augment with regard to the amount of solid phase in the liquid on page 11-12 is immaterial to the limitations of the instant claims.

12. With regards to the discharge of the liquid towards a container's inclination, applicant has insufficiently addressed the combination of references applied above in the rejection of the claims, and has only discusses Knobel and JP' 357 individually. Thus such arguments are unpersuasive.

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1723

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G. Soohoo whose telephone number is (571) 272 1147. The examiner can normally be reached on 7-5PM, Tue-Fri.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Tony G Soohoo

**TONY G. SOOHOO**  
**PRIMARY EXAMINER**

1723